III. REMARKS

A. Status of the Claims

Claims 1-4, 6-18, 22-25, 27-40, 42-44 and 47 are pending. Claims 1, 9, 22 and 28 have been amended. Claim 5 has been cancelled.

B. Election/Restrictions

In the Office Action, the Examiner repeated the Restriction Requirement and Election of species requirement previously set forth in the previous Office Action mailed on January 24, 2003 and responded to by Applicants on March 12, 2003.

1. Restriction Requirement

In response to the Restriction Requirement, Applicants again hereby elect, without traverse, Group I, claims 1-18 and 22-47, drawn to a method of treating benign prostatic hypertrophy transdermally with terazosin, classified in class 424, subclass 449.

2. Election Requirement

In response to the election of species requirement under 35 U.S.C. 121, Applicants again hereby elect without traverse the following patentably distinct species of the claimed invention:

the backing layer material:	a flexible material
polymeric matrix:	silicone
softening agent:	glycol and glycanol

C. Rejections under 35 U.S.C. § 103(a)

In the Office Action, claims 1-18, 22-25, 27-40, 42-44 and 47 were rejected under 35 U.S.C. § 103(a) as being unpatentable over United States Patent No. 5,843,472 to Ma, et al. (the Ma patent) in view of United States Patent No. 5,879,701 to Audett, et al. (the Audett patent). The Examiner

stated that the Ma patent "discloses a transdermal device useful in the treatment of benign prostatic hypertrophy (BPH). The Examiner further stated that "what the [Ma] reference is lacking is a disclosure of terazosin as the active agent and that "Audett, et al. discloses a transdermal formulation device comprising a polymeric matrix, an impermeable yet flexible backing layer, a release liner and terazosin as an active basic drug ingredient." The Examiner asserted that a skilled artisan would be able to optimize the release and permeation of the drugs into the skin.

This rejection is respectfully traversed. The Examiner relies on the Ma patent which purportedly describes a transdermal device for the treatment of benign prostatic hypertrophy containing tamsulosin as the active ingredient. At page 5 of the Office Action, the Examiner acknowledges that the active ingredient of the present invention, i.e. terazosin, is not disclosed. Further, it is respectfully submitted that although mean (average) flux rates are described at column 15, line 56 of the Ma patent, the greatest mean flux rate described in the Ma patent is 0.658 $\mu g/cm^2/hr$.

The present invention is directed, in pertinent part, to methods of treating benign prostatic hypertrophy in a human patient comprising administering terazosin transdermally by "applying a transdermal delivery system containing terazosin . . . wherein the system provides a mean relative release rate from about 1.0 $\mu g/hour/cm^2$ to about 30 $\mu g/hour/cm^2$ of said terazosin ... " and compositions thereof. It is respectfully submitted that the Ma patent fails in the very least to teach, hint or suggest the mean relative release rate recited in the present claims for the administration of terazosin as the greatest mean flux rate described in the Ma patent is 0.658 $\mu g/cm^2/hr$.

To cure the deficiencies of the Ma patent, the Examiner relies on the Audett patent, which lists terazosin in a list of active agents at column 4, lines 5-29. The Audett patent does not provide any example of a preparation of a transdermal delivery device containing an active ingredient other than tamsulosin and it is respectfully submitted that there is no indication in the Audett patent that a terazosin transdermal delivery device was ever made. Although the flux rates for tamsulosin

transdermal devices are depicted in Figures 3 and 4 of the Audett patent, it is respectfully submitted that the Audett patent fails in the very least to teach or suggest a mean relative release rate of 1.0 μg/hour/cm^2 to about 30 μg/hour/cm^2 of terazosin over the entire dosing interval as recited by the present independent claims.

Therefore, the Audett patent fails to cure the deficiencies of Ma patent as described above. It is respectfully submitted that the claimed mean relative release rate recited in the present claims is not taught, hinted or suggested by the Ma or Audett patents alone or in combination.

D. Rejections under Doctrine of Inherency

With respect to rejections under the doctrine of inherency, it is noted that the Federal Circuit stated the following in *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1268-69, 20 U.S.P.Q.2d 1746, 1749 (Fed. Cir. 1991):

> *Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient.*

In view of the above, it is respectfully submitted that the Examiner has not established that the claimed characteristics not present in the prior art necessarily flow from the cited prior art references. For example, it is possible that a mean relative release rate from the prior art could be below about 1.0 μg/hour/cm^2 or above about 30 μg/hour/cm^2. In fact, the Ma patent reports mean relative release rates which are different than recited in the claims (see column 15, line 56 of the Ma patent wherein the greatest mean flux rate described is 0.658 μg/cm^2/hr). Therefore, it cannot be concluded that a mean relative release rate of about 1.0 μg/hour/cm^2 to about 30 μg/hour/cm^2 is the natural result of the prior art, when the prior art reports different release rates.

Further, it is respectfully submitted that the cited references provide no indication that terazosin transdermal delivery devices were ever made. Therefore, the doctrine of inherency based on these references cannot be relied upon for the present claims as one cannot establish the inherent characteristics of a composition that was never made as obviousness and anticipation are separate and distinct concepts. (See Trintec Indus., Inc. v. Top-U.S.A. Corp., 295 F.3d 1292, 1296 (C.A.F.C., 2002).

In view of the amendments made and arguments presented, withdrawal of the Examiner's rejections is respectfully requested.

IV. CONCLUSION

Applicants respectfully submit that the pending claims are in condition for allowance. An early and favorable Action on the merits is earnestly solicited.

Respectfully submitted,
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